

III. Claims 30-32, 46-48, drawn to polymer microspheres, classified in class 427, subclass 213.3.

This instant application is a national stage application under 35 U.S.C. 371 of PCT International Application PCT/US99/14869. As such, unity of invention, rather than restriction, practice is applicable. See MPEP §1893.03(d). Rule 13 (Unity of Invention) of the Regulations under the PCT states that the requirement of unity is fulfilled when “there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.” See Rule 13.2, Regulations under the PCT. Unity of Invention practice is also governed by MPEP §1893.03(d), which states in part:

*When making a lack of unity of invention requirement, the examiner **must** (1) list the different groups of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) specifically describing the unique special technical feature in each group.*

(Emphasis added) MPEP 1893.03(d).

A Unity of Invention determination made for the Preliminary Search Report and the Preliminary Examination Report is not binding on the present Examiner. Applicant notes, however, that the current restriction now alleges that the pending claims (16-48) of the present application are directed to an additional invention not alleged by the International Preliminary Examining Authority (the invention of pending claims 30-32 and 46-48).

Applicant respectfully submits that the Examiner has not carried his burden to support the restriction requirement. MPEP §803 states that “under the statute an application may properly be required to be restricted...only if [the separate inventions] are able to support separate patents and

they are either independent...or distinct. If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.” Section 803 places the initial burden on the Examiner and obligates an Examiner to “provide reasons and/or examples to support conclusions.” The Examiner fails to provide reasons for his conclusion that the inventions are unrelated, pursuant to §808.01, and merely submits his conclusion as his reason for his finding, i.e. that the inventions are unrelated because they are unrelated.

In the instant Action, no indication is given as to the reasoning behind the allegation of lack of unity of each group with the others of Groups I-III. Such reasoning, as stated previously, is required under MPEP §1893.03(d). No art is cited in support of allocation of the claims to the alleged distinct inventions.

The claims of the present application are all directed to a process for preparing biodegradable microspheres and or nanospheres using an oil-in-water process which microspheres and nanospheres can be used for the controlled release of bioactive peptides. The Examiner does not rebut this stated relationship and merely asserts, without support, that since the methods of Groups I and II differ in the use of the anionic counterion the inventions are distinct. The Examiner states that his reason for concluding that the inventions are unrelated is that the classified inventions “have different modes and are not disclosed as capable of use together.” The Examiner concludes that because “the methods do not rely upon each other for their ultimate use”, “require non-coextensive literature searches” and “[have] separate patentability and enablement requirements,” restriction of the two claimed methods of Groups I and II is warranted. With respect to the product of Group III, the Examiner alleges that because the Group I and II methods

are distinct and further since the product of Group III “can be made by other methods, e.g., mixing and grinding,” the product composition is a patentably distinct invention.

Under §808, where the related inventions are alleged to be distinct, the Examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following:

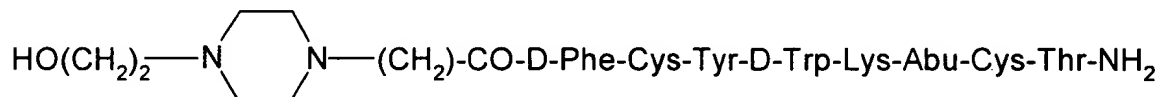
- (A) Separate classification thereof;
- (B) A separate status in the art when they are classifiable together; or
- (C) A different field of search.

Applicant notes that the Examiner has classified the three alleged inventions as not only falling within all the same classes, but also within all the same subclasses. Thus the Examiner’s allegation that these inventions are distinct and have “acquired a separate status in the art because of their *recognized divergent* subject matter” is clearly unsupported. With respect to requirement §808.02(b), to support a finding of separate status in the art when inventions are classified together, the Examiner must show either a recognition of separate inventive effort by the inventors or by citing patents which are evidence of such separate status. In the instant Action, the Examiner fails to comply with either requirement. Finally, the Examiner alleges, but provides no showing, that a different field of search is required. Pursuant to §808.02, “where the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reason exists for dividing among related invention.” In light of the foregoing, it is clear that the Examiner has failed to overcome his burden to show that examination without serious burden can not be made, and as such must examine the entire application on the merits as directed by MPEP §803.

With respect to the Examiner's conclusion that the composition claims constitute a separate invention under MPEP §806.05(f), Applicant respectfully submits that the Examiner fails to clarify how one could grind a fragile peptide, such as somatostatin, and mix it with polymer to produce a viable microspheres. Applicant contends that the Examiner's proposed alternative process is counterintuitive and that the Examiner has not demonstrated how the claimed microspheres could be made by another *materially different* process as required by MPEP §806.05(f). The burden to document a *viable alternative process* now shifts to the Examiner as required by said section of the MPEP.

For the foregoing reasons, the Applicant submits that the restriction made in the instant Action was improper and respectfully requests reconsideration that restriction and a delineation of reasoned support for distinguishing each group determined as lacking unity with each other group, as required under MPEP §1893.03(d).

In compliance with 37 C.F.R. §1.143, the Applicant elects the invention of Group II, i.e., claims 33-35 and elect as the examined species the second peptide listed in claim 28:

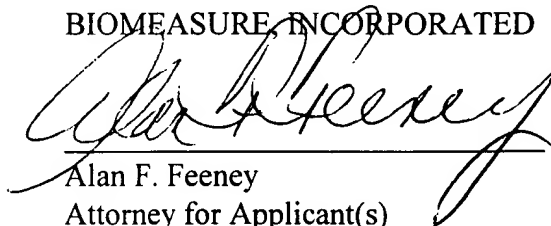


Prompt and favorable action is solicited. Should Examiner Borin deem that any further action be desirable with respect to these matters, he is requested to telephone the Applicant's undersigned representative.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-0590.

Respectfully submitted,

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